

Advanced service – Community pharmacy COVID-19 lateral flow device distribution service

Advanced service specification

29 March 2021

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1. Background and service aims

Background

- 1.1 COVID-19 lateral flow antigen tests allow the detection of people with high levels of the COVID-19 virus, making them effective in identifying individuals who are most likely to transmit the virus, including those not showing symptoms. With up to a third of infected individuals not displaying symptoms, broadening asymptomatic testing is essential. Increased use of lateral flow devices (LFD) can help identify more people who are highly likely to spread the virus, and therefore break the chain of transmission.
- 1.2 Research by NHS Test and Trace into routine mass testing shows participants prefer to access testing in the community. Pharmacists are trusted by their local communities and unfamiliar new points of access are less trusted.
- 1.3 NHS Test and Trace is making available through this service lateral flow devices (LFD) for collection from a community pharmacy.

Service aims

- 1.3 The purpose of the Community Pharmacy COVID-19 Lateral Flow Device Distribution Service is to improve access to testing by making LFD test kits readily available at community pharmacies for asymptomatic people, to identify positive cases in the community and break the chain of transmission.
- 1.4 This service will work alongside existing NHS Test and Trace COVID-19 testing routes.
- 1.5 Tests will be administered away from the pharmacy. The pharmacy will not be involved in the generation or communication of results. Pharmacy teams will not be required to support the communication of results or next steps to the person taking the test.

2. Service sign-up

- 2.1 Prior to provision of the service, the pharmacy contractor must:

- a. be complying with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential services and an acceptable system of clinical governance
 - b. sign up to the service by completing a registration declaration through the NHS Business Services Authority (NHSBSA) Manage Your Service (MYS) portal <https://services.nhsbsa.nhs.uk/nhs-prescription-services-submissions/login>
 - c. be satisfied that all pharmacy staff involved in the provision of the service are competent to do so
 - d. have a suitable place away from members of the public to store test kits ordered from the wholesaler
- 2.2 All contractors will be automatically uploaded onto the NHS Test and Trace Site Finder map <https://maps.test-and-trace.nhs.uk/> as a participating pharmacy for the LFD collect service once they sign up to deliver the service.
- 2.3 The pharmacy contractor will be hidden from public view on the map until the service is live in England. If a pharmacy contractor registers after that date they will be automatically displayed on the map.
- 2.4 All details for pharmacy contractors will be managed by the NHS Test & Trace team. If individual pharmacy contractors wish to manage their data for their sites on the map they can request to do so by emailing PharmacyCollect@dhsc.gov.uk. In order to do so pharmacy contractors must ensure they have access to a mobile phone for logging in as the service employs 2 factor authentications by sending a unique code to the registered mobile phone.
- 2.5 If a pharmacy contractor wishes to amend/update any details they see displayed on the map they can do so by emailing the request to PharmacyCollect@dhsc.gov.uk.
- 2.6 Pharmacy contractors who sign up to provide the advanced service before the end of 18th April 2021 and who deliver the service until 30th June 2021 will qualify for a single early sign-up payment of £200.

- 2.7 If contractors fail to deliver the service until 30th June 2021 (unless previously agreed with NHS Test and Trace due to extenuating circumstances), this fee will be recovered in full.
- 2.8 This service will be reviewed at the end of June 2021. This will allow the specification to be updated in light of possible insight from user engagement with this testing route.

3. Operational process

Annex A illustrates the end-to-end operational model for the distribution service, which is split into the following key areas:

Supply of tests kits to the pharmacy

- 3.1 Pharmacy contractors will need to place the first order of test kits after sign-up via a participating wholesaler in the normal way. A list of participating wholesalers can be found on the NHSBSA website [Dispensing Contractors - information | NHSBSA](#). Test kits will be supplied free of charge to pharmacies providing the service as part of their standard deliveries from the wholesaler. Pharmacy contractors will need to be aware stock ordered may not arrive with your next delivery and plan accordingly
- 3.2 The test kits are supplied in cartons containing 54 boxes, with each box (for an individual person) containing seven test kits. The carton dimensions are 50 x 29 x 40.5 cm.
- 3.3 Initial demand for test kits will be difficult to predict and pharmacy contractors will be able to order and re-order appropriate quantities of kits in line with the demand of the population they serve, up to an initial weekly order limit of 12 cartons (two cartons per day, assuming a six-day working week). This equates to a maximum of 648 boxes of seven tests handed out in a six-day week. The weekly order limit is subject to review.
- 3.4 To comply with Medicines and Healthcare products Regulatory Agency (MHRA) product recall provisions, on receipt of cartons from wholesalers, contractors must make a record of the following, which is retained for 6 months from the date on which the stock was delivered:

- LOT Number (e.g. A1234567)
- Quantity of cartons (xx Cartons)
- Supplying wholesaler (variable)
- Date of receipt (DD/MM/YY)

This data must also be entered into the MYS portal by the close of business on the pharmacy's last trading day of the week.

- 3.5 The quantities of test kit boxes ordered and supplied to the public will be monitored and reviewed as part of the post-payment verification process.

Storage

- 3.6 Test kits need to be stored in conditions that will preserve the integrity of the swab. When storing for prolonged periods, test kits should be stored in a designated area away from direct sunlight, between 2°C and 30°C.

Distribution service

- 3.7 The test kits will be provided free of charge to people requesting them.
- 3.8 Contractors can supply one box of test kits per individual. If the person is also collecting on behalf of one additional person, contractors can hand out two boxes per transaction. Up to four boxes may be provided per transaction by pharmacy teams acting under the professional discretion of a pharmacist.
- 3.9 Each box contains seven LFDs. This allows the person to test themselves twice weekly over a three-week timeframe. This number of tests in the box factors in the potential for a void test.
- 3.10 There is no minimum age for use of LFD test kits.
- 3.11 The Test and Trace minimum recommended age for a person to collect LFD test kits is 18 years, but where necessary professional judgement can be applied by pharmacy contractors.
- 3.12 Tests must be conducted and results registered away from the pharmacy, as explained in the instructions inside the test kit. People undertaking a test can contact 119 for assistance with using the kit or to register their result.

- 3.13 If the pharmacy temporarily runs out of test kits or experiences a demand for test kits it cannot meet at that time, contractors have the option to change their information on the online NHS COVID Test Finder tool <https://maps.test-and-trace.nhs.uk> by emailing PharmacyCollect@dhsc.gov.uk and requesting for their site to be displayed as 'out of stock'.

Service pathway

- 3.14 The pharmacy must ask the person collecting the test kits the following **three questions**. The answers to questions 2 and 3 must be entered into the MYS portal by the close of business on the pharmacy's last trading day of the week.

Question 1: Have you collected LFD test kits before?

- If the person answers yes, please reiterate message 3.18 iv below on the need to register results, whether positive or negative.

Question 2: Why do you need tests? (only in relation to the first person requesting a test)

- i. My child is at school/I work at a school/I am in a bubble with school children or staff.
- ii. I leave the house for work.
- iii. My local council advised me to test.
- iv. My GP/healthcare professional advised me to test.
- v. Other (free text response).

Question 3: What is the age range of the person using the kit?

Under 18; 18–24; 25–34; 35–44; 45–54; 55–64; 65 and over.

- i. person 1
- ii. person 2
- iii. person 3
- iv. person 4.

- 3.15 The data entered into MYS will be used for evaluation and service improvement purposes and it will also populate the end of month payment claim.

- 3.16 Pharmacy staff must ensure the person collecting the test kits understands the following **key points**:
- i. The tests help identify people who are positive for COVID-19 but do not have symptoms.
 - ii. **A negative result does not guarantee someone does not have COVID-19. It is important to continue following government guidelines and restrictions.**
 - iii. Instructions on how to use the test and report your results are inside the box.
 - iv. **It is important to report your results, whether positive or negative.**
This is because reporting results helps the NHS identify areas where asymptomatic cases of COVID-19 are rising and declining, so we can all keep each other safe. When you report your result, you will be provided with information on the next steps you need to take.

If a person indicates that they have not previously reported their results, it is particularly important to reiterate the importance of doing so for the new tests being supplied.
 - v. You must make a note of the lot number of the test kit used, in case you need to report any incidents related to the device, test instructions, harm or injury. The instructions inside the box give details on how you can report any incidents.
- 3.17 If a pharmacy is contacted by a person with a query about the device, test instructions, harm, injury or results, it should direct them to 119, and report any incidents as described in Section 5.
- 3.18 In the event of a recall, contractors must display information on any safety recalls/concerns using posters provided by NHS Test and Trace. Where a pharmacy can share this information using social media channels, that communication route to the public can also be used.

4. Service availability

- 4.1 The contractor must seek to ensure that the service is available throughout the pharmacy's core and supplementary opening hours.

- 4.2 The contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible person should be excluded or experience difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.
- 4.3 The contractor must have a standard operating procedure (SOP) for provision of the service and all pharmacy staff involved in the provision of the service must be familiar with the SOP.
- 4.4 If there is a problem with the service, the contractor should contact the NHS Test and Trace support team by calling 119.
- 4.5 If the contractor wishes to stop providing the service, this can be done via the MYS platform. The contractor must give at least one month's notice.

5. Clinical governance

- 5.1 The pharmacy governance lead (nominated individual in the pharmacy) must provide feedback about any incidents relating to patient safety, the referral process or operational issues with respect to the service by emailing the NHS England and NHS Improvement Central Community Pharmacy mailbox (england.communitypharmacy@nhs.net).
- 5.2 To comply with MHRA governance requirements, in the event of any incidents with respect to the test kits, the contractor must provide feedback to NHS Test and Trace via email (integrator@dhsc.gov.uk). Feedback must be submitted by 11am on Monday mornings for incidents that occurred in the preceding week.
- 5.3 The contractor is required to report any patient safety incidents in line with the Clinical Governance Approved Particulars for pharmacies. The pharmacy contractor should also make Yellow Card reports to MHRA, as necessary (see guidance at <https://coronavirus-yellowcard.mhra.gov.uk/>).
- 5.4 Any information supplied to NHS Test and Trace or NHS England and NHS Improvement must be anonymised and not contain any patient identifiable information.

6. Payment

- 6.1 Payments for this service will be calculated from the weekly MYS submissions detailed in paragraph 3.15 above, made via the NHSBSA MYS portal from the submissions received at the end of the fifth day of the following month in line with the Drug Tariff. Contractors do not have to claim for payments for this service.
- 6.2 NHSBSA will make appropriate payments, to the contractor, corresponding to the weekly cycle, on the same payment date as other payments for NHS Pharmaceutical Services. The payments will be separately itemised on the FP34 Schedule of Payments.
- 6.3 Payment for provision of the service will be made up of the following elements:
- i. An early sign-up fee of £200 + an allowance for VAT, for any contractors who sign up to deliver the service before the end of 18th April 2021. This payment will be triggered by completion of the registration declaration on the MYS portal by the end of 18th April 2021.
 - ii. A one-off set-up fee of £250 + an allowance for VAT, which covers set-up costs including creating an SOP for the service and training staff who will be involved in providing the service, and storage costs for the test kits ordered from wholesalers. This payment will be triggered by completion of the registration declaration on the MYS portal.
 - iii. A service fee of £1.50 + an allowance for VAT per transaction. This payment will be made based on declarations submitted by the contractor on the MYS portal.

Annex A: End-to-end service model

